REMARKS

By this Amendment, Claims 1-4, 8-10 and 14-15 are amended. Claims 5-7, 13 and 16-21 have been cancelled to expedite the prosecution of this application. Claims 1-4, 8-12 and 14-15 are pending.

In the Final Office Action of parent application A.S.N. 09/439,879, the Examiner rejected Claims 1-4, 10-12, and 14 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,814,020 (Gross, hereinafter the "'020 patent"). In particular, the Examiner asserts that:

> Gross discloses a housing (10) having a penetrating member aperture (no reference numeral, see Figure 2) having a first longitudinal axis, a port (20) that receives a rigid container (19) housing a drug (24) having a second longitudinal axis, the container including a pressurizing mechanism defined as the ability of the piston (25) to move relative to the container thereby causing pressure to expel the drug in order to deliver it to a chamber (12) including a gas impermeable sealing member (18), a first penetrating member (14) movable from a storage position (see Figure 2) to an injection position (see Figure 4), a channel (22, 23, 12) within a manifold (no reference numeral, see Figure 2) that brings the penetrating member into fluid communication with the container via a second channel (13), wherein the first longitudinal axis and the second longitudinal axis are not parallel nor coaxial. The first penetrating member can effect intradermal, transcutaneous or intramuscular delivery. (Office action, p. 2).

However, in view of the amendments to Claims 1 and 10, Applicants respectfully submit that Claims 1 and 10 are patentable over the art of record for the following reasons.

As amended, Claims 1 and 10 now specify that the container received in the housing port is a *standard* container. The drug container of the present invention is any *standard* drug vial, thereby

making the present invention adaptable for use with existing drug vials[1]. In contrast, the drug container 19 of the '020 patent is a *customized* drug container designed for use with the drug delivery device of the '020 patent. As a result, this structural difference makes the present invention more easy to use and less costly to use, among other things. Moreover, the device of the '020 patent is similar to an *infusion* pump, i.e., the device is coupled to the living being and the drug is *automatically pressurized by an internal gas generator*[2] that drives the drug through the needle to accomplish delivery and the device does this on a *continuous* basis; thus, the user has no part in pressurizing the drug other than to press a start button to energize a gas generating electrolytic cell. In contrast, the present invention, the user operates a "compression means" (also referred to as a "manually-driven pressurizing mechanism") that compresses air to pressurize the drug in the standard container. In particular, the compressed air is generated *by the user* causing a rubber stopper 118 in diluent container 116 to compress the contents of the container as the container is moved into a receiving port; thus, it is the user that pressurizes the drug in the standard container. This additional structure further distinguishes the present invention from the device of the '020 patent. Therefore, for all of the above reasons, Claims 1 and 10 are patentable over the art of record and Applicants respectfully request that the §102(b) rejection be withdrawn.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons.

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[1]Advantageously, the device 100 utilizes a standard vial or first storage container 102, which contains the lyophilized drug or compound 164, and a standard cartridge or second storage container 116, which contains the diluent 166. (Present application, p. 12, lines 10-12).

[2]'020 patent, col. 11, lines 51-58.

Claim 3 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 4 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 11 is dependent upon Claim 10 and is patentable for the same reasons.

Claim 12 is dependent upon Claim 11 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 10 and is patentable for the same reasons.

The Examiner has rejected Claims 8, 9, 15, 20 and 21 under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,814,020 (Gross, hereinafter the "'020 patent") in view of U.S. Patent No. 5,873,856 (Hjertman et al.). In particular, the Examiner asserts that:

> Gross discloses a housing (10) having a penetrating member aperture (no reference numeral, see Figure 2) having a first longitudinal axis, a port (20) that receives a rigid container (19) housing a drug (24) having a second longitudinal axis, the container including a pressurizing mechanism defined as the ability of the piston (25) to move relative to the container thereby causing pressure to expel the drug in order to deliver it to a chamber (12) including a gas impermeable sealing member (18), a first penetrating member (14) movable from a storage position (see Figure 2) to an injection position (see Figure 4), a channel (22, 23, 12) within a manifold (no reference numeral, see Figure 2) that brings the penetrating member into fluid communication with the container via a second channel (13), wherein the first longitudinal axis and the second longitudinal axis are not parallel nor coaxial. The first penetrating member can effect intradermal, transcutaneous or intramuscular delivery. See Column 6, line 66 through Column 7, lines 1-32 for exemplary fluids to be injected, such as insulin.
>
> Gross fails to explicitly recite the penetrating member extending 5-12 mm out of the housing, the penetrating member extending 3 cm out of the housing, and a method of delivering a drug in one dose on a one-time basis.
>
> Hjertman et al. discloses an injection pen for delivering insulin which can be a conventional single dose syringe or an injection pen containing multiple doses connected to a dosing device, see Column 1, line 32 and Column 2, lines 36-38. The injection pen can be adjusted to control the depth of injection depending upon the

> therapeutic application, see Column 3, lines 47-50 and Column 3, line 60 through Column 4, line 4.
>
> It would have been obvious to one having ordinary skill in the art to have modified Gross' device so as to enable one dose delivery on a one-time basis, as taught by Hjertman et al., so as to enable the tailoring of the device to a variety of therapeutic applications, including insulin delivery or epinephrine delivery which require rapid, one-time delivery in emergency situations. Additionally, it would have been obvious to one having ordinary skill in the art to have modified Gross' device with the ability to vary the extended length of the penetrating member, as taught by Hjertman et al. so as to enable a user to target a specific tissue, i.e., intradermal delivery would require a shorter needle than intramuscular delivery. (Office action, pp. 3-4).

However, Applicants disagree for the following reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 9 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 15 has been amended in accordance with Claims 1 and 10 and is patentable for the same reasons.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.